

Appl. No. : 10/674,553  
Filed : September 30, 2003

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### REMARKS

Claims 1-5, 38-50, 55-61, 63, 64, 66-71, and 85-91 are pending. With the present Response, Claims 120-180 are added; therefore, Claims 1-5, 33-41, 55-61, 63, 64, 66-71, 85-91 and 120-180 remain pending for consideration.

#### Claim Rejections Under 35 U.S.C. § 102

Claims 1-5 and 85-91 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,865,791 to Whayne, et al. Although Applicants do not acquiesce to the Office Action's rejections, in order to expedite prosecution, Applicants have amended Claims 1 and 85; however, Applicants reserve the right to pursue previous versions of Claims 1 and 85 in the future. Applicants respectfully traverse the rejections because Whayne fails to teach or suggest all of the claim language.

Claim 1 has been amended to recite, inter alia, "providing a deployment catheter having . . . an implantable device . . . comprising a barrier, said device . . . configured to conform to an inside surface of the left atrial appendage; . . . and enlarging the device within the left atrial appendage, wherein said barrier extends across the left atrial appendage when enlarged so that the device circumferentially seals against the inside surface of the left atrial appendage."

Whayne fails to teach or suggest providing a catheter having an implantable device that comprises a barrier that conforms to an inside surface of the left atrial appendage, a barrier that extends across the left atrial appendage when enlarged, or a device that circumferentially seals against the inside surface of the left atrial appendage.

Therefore, Claim 1 distinguishes over Whayne. Claims 1-5 depend from Claim 1 and therefore distinguish over Whayne as well. Claims 2-5 are also allowable because of the unique combination of features recited therein.

Claim 85 has been amended to recite, inter alia, "placing the implantable structure in circumferential sealing contact with a tissue surface adjacent the opening of the atrial appendage."

Whayne fails to teach or suggest placing an implantable structure in circumferential sealing contact with a tissue surface adjacent the opening of the atrial appendage.

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Therefore, Claim 85 distinguishes over Whayne. Claims 86-91 depend from Claim 85 and therefore distinguish over Whayne as well. Claims 86-91 are allowable because of the unique combination of features recited therein.

### Claim Rejections Under 35 U.S.C. § 103

Claims 38-43, 45-50, 55-61, 63, 64, and 66-71 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Whayne in view of U.S. Patent No. 5,375,612 to Cottenceau, et al. Applicants respectfully traverse the rejection.

Section 2143 of the M.P.E.P. states that to establish an obviousness three requirements must be met:

First, there must be some suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the Applicant's disclosure.

The Office Action provides, "[Cottenceau] discloses the use of anchors 19 on an intravascular device. It would have been obvious to have provided Whayne's device with anchoring elements to prevent the movement of the mesh within the LA." Office Action of October 2, 2006, page 4. However, the Office Action fails to provide any suggestion or motivation, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the Whayne reference or to combine it with Cottenceau. For example, Cottenceau describes "possibly absorbable blood filter[s]" that are "at least partly biologically absorbable," and that can be used in the vena cava. Cottenceau, at column 1, lines 1, and 64-68, and column 3, lines 24-30. One would not be motivated to combine such a reference with the left atrial appendage devices and methods described by Whayne at least because of the great difference in clinical therapies as well as device structures described. Furthermore, there is no indication in Whayne to consider the possibility of the purse string failing, and even if it did, there is no reason to believe from Whayne that anchors or barbs should or could be used to attach or secure the mesh.

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Moreover, there is no motivation to add anchors to the mesh to prevent the movement of the mesh within the LAA", as suggested by the Office Action on page 4, because there is no indication that Whayne's purse-string-like arrangement is inadequate to do so without anchors, or even that it would be desirable to do so. Indeed, Whayne's purse-string arrangement suggests that additional prevention of movement of a mesh within an LAA would not be desirable or necessary as the purse-string arrangement itself appears to provide such a result.

Rather than finding motivation from the references or the knowledge of one of skill in the art, it appears that the Office Action has impermissibly used hindsight derived from the teachings in the present application, and not the teachings of the prior art, to reject Applicants' claims. *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999) (holding the Board impermissibly used hindsight in determining obviousness); *see also*, M.P.E.P. § 2141, part X.A. In *Dembiczak*, the Federal Circuit reiterated that a determination of obviousness cannot simply rely on the inventor's disclosure as a "blueprint" without evidence of a suggestion, teaching or motivation in the prior art. *Dembiczak*, at 999. Also, according to M.P.E.P. § 706.02(j) "[t]he teaching and suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on the Applicant's disclosure." (Emphasis added).

Similarly, the Office Action fails to provide any evidence that there would be a reasonable expectation of success. Cottenceau provides no teaching or suggestion that its anchoring barbs could be provided Whayne's mesh 95. In addition, none of the references provides any teaching or suggestion as to how such barbs would actually be provided on Whayne's mesh 95.

The Applicants therefore respectfully submit that the rejected claims patentably distinguish over the applied art and respectfully requests allowance of Claims 38 and 56. Claims 39-42, 45-49, and 55 depend from Claim 38, and Claims 57-61, 63, 64, and 66-71 depend from Claim 56; therefore these claims distinguish over the applied art for at least these reasons as well. In addition, these dependent claims are allowable for the unique combination of features recited therein.

In addition, Claim 50 depends from Claim 1 and therefore distinguishes over the applied art for at least the reasons provided above. Furthermore, Claim 51 distinguishes over the applied art for the unique combination of features recited therein.

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### **Double Patenting**

Claims 1-5, 38-50, 55-61, 63, 64, 66-71, and 85-91 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over the claims of copending Application Nos. 10/364,910, 10/830,964, and 10/093,012. Applicants submit a terminal disclaimer with this response and therefore request withdrawal of the double patenting rejection.

### **New Claims**

New Claims 120-178 correspond to previously canceled claims 6-11, 51, 14-18, 52, 22-24, 28, 29, 53, 30-33, 54, 77-84, 92-103, 105-111, and 113-120, respectively, which were canceled in the Response filed August 30, 2006 in order to expedite allowance of the claims that had previously been indicated as allowable. However, since the Office action of October 2, 2006 has now rejected the previously-allowed claims, Applicants have re-presented the previously canceled claims indicated above for reconsideration.

New Claims 120-178 are all allowable over the applied art for at least the reasons provided in the Response filed February 23, 2006, as well as for at least the reasons further provided above with respect to the other pending claims.

For example, Claim 120 distinguishes over the applied art at least because none of the applied art teaches or suggests providing an implantable device having a barrier, positioning the implantable device in the left atrial appendage while the device is in its collapsed configuration; and enlarging the implantable device in the left atrial appendage wherein the barrier extends across the longitudinal axis when the implantable device is enlarged. Claims 121-127 depend from Claim 120, and therefore distinguish over the applied art for at least the same reasons. In addition, these claims distinguish over the applied art for the unique combination of features recited therein.

Claim 128 distinguishes over the applied art at least because none of the applied art teaches or suggests advancing a catheter through a patient until the distal end is disposed adjacent the opening of the patient's left atrial appendage; and releasing a device, the device configured to block an opening to the left atrial appendage to prevent passage of embolic material from the left

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atrial appendage. Claims 129-133 depend from Claim 128, and therefore distinguish over the applied art for at least the same reasons. In addition, these claims distinguish over the applied art for the unique combination of features recited therein.

Claim 134 distinguishes over the applied art at least because none of the applied art teaches or suggests positioning a device in the left atrial appendage and securing the device, the device configured to prevent passage of emboli from the left atrial appendage, wherein the device conforms to an inside wall of the left atrial appendage. Claims 135-139 depend from Claim 134, and therefore distinguish over the applied art for at least the same reasons. In addition, these claims distinguish over the applied art for the unique combination of features recited therein.

Claim 140 distinguishes over the applied art at least because none of the applied art teaches or suggests providing a barrier carried by the implantable device across the left atrial appendage. Claims 141-144 depend from Claim 140, and therefore distinguish over the applied art for at least the same reasons. In addition, these claims distinguish over the applied art for the unique combination of features recited therein.

Claim 145 distinguishes over the applied art at least because none of the applied art teaches or suggests positioning an implantable structure adjacent the opening of the atrial appendage, wherein the structure conforms to an inner wall tissue surface when enlarged. Claims 146-152 depend from Claim 145, and therefore distinguish over the applied art for at least the same reasons. In addition, these claims distinguish over the applied art for the unique combination of features recited therein.

Claim 153 distinguishes over the applied art at least because none of the applied art teaches or suggests providing an implantable structure positioned adjacent the opening of the atrial appendage, the enlarged configuration blocking the opening of the atrial appendage; and changing the configuration of the structure at the atrial appendage. Claims 154-157 depend from Claim 153, and therefore distinguish over the applied art for at least the same reasons. In addition, these claims distinguish over the applied art for the unique combination of features recited therein.

Claim 158 distinguishes over the applied art at least because none of the applied art teaches or suggests deploying an implantable structure at the atrial appendage with a delivery device positioned at the atrial appendage, the structure being configured to block an opening of

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the atrial appendage. Claims 159-169 depend from Claim 158, and therefore distinguish over the applied art for at least the same reasons. In addition, these claims distinguish over the applied art for the unique combination of features recited therein.

Claim 170 distinguishes over the applied art at least because none of the applied art teaches or suggests positioning a device at the atrial appendage. The device when positioned having at least a portion that generally conforms to an inside surface of the atrial appendage. Claims 171-178 depend from Claim 170, and therefore distinguish over the applied art for at least the same reasons. In addition, these claims distinguish over the applied art for the unique combination of features recited therein.

Finally, Claim 179 and 180 depend from Claims 1 and 5, respectively, and therefore distinguishes over the applied art for at least the reasons provided above. Furthermore, Claims 179 and 180 distinguish over the applied art for the unique combination of features recited therein.

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**CONCLUSION**

In view of the foregoing amendments and remarks, Applicant submits that this application is in condition for allowance and such action is respectfully requested. If any issues remain or require further clarification the Examiner is respectfully requested to call Applicant's counsel at the number indicated below in order to resolve such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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